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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Peter ERDMANN et al.	Confirmation No.: 7310
Patent No.: 6,787,158 B1	Application No.: 09/450,217
Patent Date: September 7, 2004	Filing Date: November 29, 1999
For: PROCESS FOR THE TREATMENT OF A LACTIC RAW MATERIAL	Attorney Docket No.: 88265-296

REQUEST FOR CERTIFICATE OF CORRECTION UNDER 37 C.F.R. § 1.322

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Patentees hereby respectfully request the issuance of a Certificate of Correction in connection with the above-identified patent. The corrections are listed on the attached Form PTO-1050, submitted in duplicate. The corrections requested are as follows:

Title page, Item (54), and Column 1, line 1:

Change the title to -- **PROCESS FOR THE TREATMENT OF A LACTIC RAW MATERIAL** --. Support for this change can be found on page 1 of the application as filed on November 29, 1999.

Column 9:

Line 5 (claim 1, line 14), after "does not contain substantial", delete ",". Support for this correction can be found in application claim 1 as amended April 1, 2004.

Line 47 (claim 5, line 16), after "to adsorb the", delete ":". Support for this correction can be found in application claim 6 as amended November 12, 2002.

The Notice of Allowability, attached to the Notice of Allowance mailed May 5, 2004, indicates that in response to the communication filed April 1, 2004, the allowed claims are 1-4, 6-18 and 21-27. On page 2 of the Notice of Allowability, the Examiner indicates that claims 14-19 and 21-23, which had previously been withdrawn, had been rejoined. Also, pursuant to an Examiner's Amendment, claims 1-4, 6-18 and 21-27 were indicated as allowable.

25 OCT 2004

In the Examiner's Amendment, appearing on pages 2-3 of the Notice of Allowability, claim 19 was canceled, claims 21-23 were amended, and new claim 27 was added in place of claim 19. Claims 21 and 22, dependent on canceled claim 19, were amended to depend from new claim 27. Claim 23 was amended to delete the phrase "further comprising the step of freeze-drying the retentate" and substitute therefore -- wherein the recovered retentate is freeze-dried. --.

In reviewing the issued patent, it is noted that only new claim 27 (renumbered as patent claim 16) was incorporated in the patent. Claims 14-18 and 21-23, which the Examiner indicated as allowable, were omitted from the patent. Therefore, it is respectfully requested that claims 14-18 and 21-23, as amended, be incorporated in the patent. Although the Examiner indicated in the Issue Classification (copy attached) that the original order of claim numbering should be retained, it is submitted that these claims be renumbered as new claims 17-24, as follows:

-- 17. The process of claim 1 wherein the treated liquid material has an amino acid profile that is reduced in threonine and enriched in aromatic amino acids and tryptophan relative to the lactic raw material. --

-- 18. The process of claim 17 wherein, relative to the lactic raw material, the threonine content is reduced by about 15 to 40%, and the aromatic amino acids and tryptophan are increased by about 20 to 60%. --

-- 19. The process of claim 17, wherein the treated liquid material is included in an infant or dietetic product as protein raw material. --

-- 20. The process of claim 9 wherein the treated liquid material is included in an infant or dietetic product as protein raw material. --

-- 21. The process of claim 10 wherein the dried treated liquid material is included in an infant or dietetic product as protein raw material. --

-- 22. The process of claim 16 wherein the composition is a food composition containing the GMP as an emulsifying, gelling or foaming agent. --

-- 23. The process of claim 16 wherein the composition is a dental composition containing the GMP as an agent against plaque and caries. --

-- 24. The process according to claim 12, further comprising the step of freeze-drying the retentate. --

There is no issue of new matter since these claims, all of which depend from allowed claims, were previously found to be allowable in the Examiner's Amendment.

It is respectfully submitted that a certificate of correction is not appropriate to make the corrections to the claims of this patent. Instead, patentees request that the Patent Office issue a corrected patent in lieu of the certificate of correction as a more appropriate form for presenting the claims in the patent. In addition, it is requested that the reprinted patent should be made at no cost to patentees.

The requested corrections are for errors that appear to have been made by the Office. Therefore, no fee is believed to be due for this request. Should any fees be required, however, please charge such fees to Winston & Strawn LLP Deposit Account No. 50-1814.

Respectfully submitted,

10/15/04
Date

Allan A. Fanucci, Reg. No. 30,256

WINSTON & STRAWN LLP
Customer No. 28765

212-294-3311

25 OCT 2004

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.: 6,787,158 B1
DATED: September 7, 2004
INVENTORS: Erdmann et al.

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

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Column 9:
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Line 47 (claim 5, line 16), after "to adsorb the", delete ":".

Please add the following claims:

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-- 24.. The process according to claim 12, further comprising the step of freeze-drying the retentate. --

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25 OCT 2004

Issue Classification	Application No.	Applicant(s)	
	09/450,217	ERDMANN ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

ISSUE CLASSIFICATION

ORIGINAL CLASS	ORIGINAL SUBCLASS	CROSS REFERENCE(S) CLASS	CROSS REFERENCE(S) SUBCLASS (ONE SUBCLASS PER BLOCK)							
424	535	426	41	657						
INTERNATIONAL CLASSIFICATION										
A61K 35/20		530	412	416	352					

David Lukton 4/29/04
(Assistant Examiner) (Date)

(Legal Instruments Examiner) (Date)

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Christopher S. Low 3 May 2004
(Primary Examiner) (Date)

Total Claims Allowed: 24

O.G. Print Claim(s): 1

O.G. Print Fig: None

☑ Claims renumbered in the same order as presented by applicant ☐ CPA ☐ T.D. ☐ R.1.47

Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original	Final	Original
	1		31		61		91		121		151		181
	2		32		62		92		122		152		182
	3		33		63		93		123		153		183
	4		34		64		94		124		154		184
	5		35		65		95		125		155		185
	6		36		66		96		126		156		186
	7		37		67		97		127		157		187
	8		38		68		98		128		158		188
	9		39		69		99		129		159		189
	10		40		70		100		130		160		190
	11		41		71		101		131		161		191
	12		42		72		102		132		162		192
	13		43		73		103		133		163		193
	14		44		74		104		134		164		194
	15		45		75		105		135		165		195
	16		46		76		106		136		166		196
	17		47		77		107		137		167		197
	18		48		78		108		138		168		198
	19		49		79		109		139		169		199
	20		50		80		110		140		170		200
	21		51		81		111		141		171		201
	22		52		82		112		142		172		202
	23		53		83		113		143		173		203
	24		54		84		114		144		174		204
	25		55		85		115		145		175		205
	26		56		86		116		146		176		206
	27		57		87		117		147		177		207
	28		58		88		118		148		178		208
	29		59		89		119		149		179		209
	30		60		90		120		150		180		210

US006787158B1

(12) **United States Patent**
Erdmann et al.

(10) **Patent No.: US 6,787,158 B1**
(45) **Date of Patent: Sep. 7, 2004**

(54) **PROCESS FOR THE TREATMENT OF A LACTIC RAW MATERIAL**

(75) Inventors: **Peter Erdmann**, Bern (CH); **Fred Neumann**, Steffisburg (CH)

(73) Assignee: **Nestec S.A.**, Vevey (CH)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/450,217**

(22) Filed: **Nov. 29, 1999**

Related U.S. Application Data

(63) Continuation-in-part of application No. PCT/EP98/03176, filed on May 22, 1998.

(30) **Foreign Application Priority Data**

May 27, 1997 (EP) 97201607

(51) **Int. Cl.**[7] **A61K 35/20**

(52) **U.S. Cl.** **424/535**; 426/41; 426/657; 530/412; 530/416; 530/352

(58) **Field of Search** 424/535; 426/41, 426/657; 530/412, 416, 352

(56) **References Cited**

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* cited by examiner

Primary Examiner—Christopher S. F. Low
Assistant Examiner—David Lukton
(74) *Attorney, Agent, or Firm*—Winston & Strawn LLP

(57) **ABSTRACT**

A process is disclosed for extracting glycomacropeptide from a lactic raw material. This process includes the step of treating a lactic raw material containing glycomacropeptide in the presence of a weakly anionic resin wherein the glycomacropeptide is selectively adsorbed onto the resin and then eluted from the resin so as to obtain an improved protein product which can be used in foods, and pharmaceutical and dental compositions.

16 Claims, 1 Drawing Sheet

PROCESS FOR TREATMENT OF A LACTIC RAW MATERIAL

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of copending PCT international application No. PCT/EP98/03176, filed on May 22, 1998.

FIELD OF THE INVENTION

The invention is directed to a process for the separation of glycomacropeptide or caseinoglycomacropeptide ("GMP") from lactic raw material.

BACKGROUND OF THE INVENTION

GMP is a phosphorylated and partially sialylated macropeptide which is formed by the action of a protease, for example rennet, on mammalian milk kappa-casein. GMP represents about 20% by weight of the proteins in sweet whey obtained after separation of casein during cheese manufacture.

A laboratory scale process for the manufacture of GMP is known. The process consists of treating a raw lactic material, such as an acid casein, a caseinate hydrolyzed by rennet, or a demineralized and lactose-free sweet whey from cheesemaking, with trichloroacetic acid so as to precipitate the proteins. The process further consists of recovering the supernatant, dialyzing the supernatant, and drying the separated dialysate. Although known, such a process is not applicable on an industrial scale.

A process for the production of GMP on an industrial scale, which is described in European Patent Application No. 488,589, consists of treating a whey product by ion exchange and recovering the fraction that has not been adsorbed. The process further consists of concentrating the fraction, demineralizing the fraction using ultrafiltration, diafiltration and, if necessary reverse osmosis, and recovering the GMP.

British Patent No. 2,188,526 discloses a process for the production of a whey protein fraction. The process consists of treating a milk product with a strong anionic resin, under conditions such that proteins and some peptides of the treated material are nonselectively adsorbed onto the resin in the form of complexes. These complexes are difficult to subsequently elute from the resin. The eluate forms a firm gel at a pH of less than 4.5 and at room temperature, once the eluate is suspended in water. The protein fraction may be used in drinks of the milk-shake type and in dessert mousses.

Japanese Patent Publication Kokai 07-132049 uses a weakly anionic ion exchange resin whose matrix is hydrophilic to separate the sialylated peptides from whey. The process consists of passing the raw material, whose pH has been beforehand precisely adjusted to a value of 4 to 6, over a hydrophilic macromolecular support consisting of a natural polysaccharide or a synthetic polyvinyl, grafted with basic exchanging groups. The supports used as matrix are not easily applicable industrially.

Despite the aforementioned processes, there is a need for a process which easily and selectively separates a highly purified GMP from lactic raw materials without additional expense and which can be conducted on a large scale. Additionally, it is highly desirable to develop a process that can separate GMP from lactic raw material in a single operation and in high yield.

SUMMARY OF THE INVENTION

The invention relates to a process for the extraction of GMP from a lactic raw material comprising the steps of removing cations from a lactic raw material for a sufficient amount of time to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5; contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to remove GMP from the substantially deionized lactic raw material and to obtain a treated liquid material; separating the resin from the treated liquid material; and rinsing the resin to obtain the GMP therefrom.

In this process, the lactic raw material can be one of sweet whey obtained after separation of casein coagulated with rennet, a concentrate of sweet whey, a sweet whey or such a whey demineralized to by electrodialysis, ion exchange, reverse osmosis, electrodeionization or a combination of these procedures, a concentrate of sweet whey demineralized by electrodialysis, ion exchange, reverse osmosis, electrodeionization or a combination of these procedures, a concentrate of proteins of substantially lactose-free sweet whey obtained by ultrafiltration, followed by diafiltration (ultrafiltration with washing), mother liquors of the crystallization of lactose from sweet whey, a permeate of ultrafiltration of a sweet whey, the product of hydrolysis, by a protease, of a native casein obtained by acid precipitation of skimmed milk with an inorganic acid or by biological acidification, where appropriate with addition of calcium ions or alternatively of a micellar casein, obtained by microfiltration of a skimmed milk, the product of hydrolysis of a caseinate by a protease. Preferably, the sweet whey has a solids content of about 10 to 23 percent by weight and is completely deionized during the cation removal step.

Also, the lactic raw material is preferably a liquid or a dispersion of solids in a liquid and calcium ions may be added to the lactic raw material after the cation removal step.

Advantageously, the resin is treated with an alkaline material prior to contact with the substantially deionized lactic raw material. Preferably, the substantially deionized lactic raw material contacts the resin in a gently stirred reactor at a temperature of less than 50° C. for one to ten hours to adsorb the GMP onto the resin. A suitable resin is one that is basic and in macroporous or macrocross-linked gel form. The substantially deionized lactic raw material usually contacts the resin until the treated liquid material attains a constant pH of between about 4.5 to 5.5 to indicate that the reaction has proceeded to completion. Advantageously, the resin and lactic raw material are present in a volume ratio of 1:1 to 1:30.

The invention also relates to the treated liquid material that is obtained from this inventive process. This treated liquid material has an amino acid profile is reduced in threonine and enriched in aromatic amino acids and tryptophan. Relative to the starting lactic raw material, the threonine content is preferably reduced by about 15 to 40%, and the aromatic amino acids and tryptophan are preferably increased by about 20 to 60%. This treated liquid material is useful in an infant or dietetic product as a protein raw material, in a pharmaceutical composition in combination with antithrombotic, antidiarrheal or antibacterial agents, or in a food composition as an emulsifying, gelling or foaming agent. The invention also produces a new GMP which can be used, for example, in a dental composition as an agent against plaque and caries.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic representation of an apparatus capable of separating GMP from lactic raw material.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is directed to a process for the selective separation of GMP from other components con-

a sufficient amount of time and at a sufficient temperature to adsorb a substantial amount of GMP onto the anionic resin from the substantially deionized lactic raw material and to obtain a treated liquid material that does not contain substantial amounts of GMP;

separating the resin from the treated liquid material; and

separating the adsorbed GMP enriched fraction from the resin.

2. The process according to claim 1 wherein the lactic raw material is one of sweet whey obtained after separation of casein coagulated with rennet, a concentrate of sweet whey, a sweet whey or such a whey demineralized to by electrodialysis, ion exchange, reverse osmosis, electrodeionization or a combination of these procedures, a concentrate of sweet whey demineralized by electrodialysis, ion exchange, reverse osmosis, electrodeionization or a combination of these procedures, a concentrate of proteins of substantially lactose-free sweet whey obtained by ultrafiltration, followed by diafiltration (ultrafiltration with washing), mother liquors of the crystallization of lactose from sweet whey, a permeate of ultrafiltration of a sweet whey, the product of hydrolysis, by a protease, of a native casein obtained by acid precipitation of skimmed milk with an inorganic acid or by biological acidification, where appropriate with addition of calcium ions or alternatively of a micellar casein, obtained by microfiltration of a skimmed milk, the product of hydrolysis of a caseinate by a protease.

3. The process according to claim 1 wherein the lactic raw material is sweet whey having a solids content of about 10 to 23 percent by weight.

4. The process according to claim 1 wherein the lactic raw material is a liquid or a dispersion of solids in a liquid.

5. A process for obtaining a fraction of lactic raw material enriched in glycomacropeptide or caseinoglycomacropeptide ("GMP") comprising the steps of:

deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5 with the pH being adjusted, if necessary, to the recited range;

contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to remove GMP from the substantially deionized lactic raw material and to obtain a treated liquid material, wherein the substantially deionized lactic raw material contacts the resin in a gently stirred reactor at a temperature of less than 50° C. for one to ten hours to adsorb the GMP onto the resin;

separating the resin from the treated liquid material; and

separating the GMP enriched fraction from the resin.

6. The process according to claim 5 wherein the reactor is at a temperature between 0° C. and 15° C. and the resin is basic and in macroporous or macrocross-linked gel form.

7. The process according to claim 1 wherein the substantially deionized lactic raw material contacts the resin until the treated liquid material attains a constant pH of about 4.5 to 5.5.

8. A process for the extraction and removal of glycomacropeptide or caseinoglycomacropeptide ("GMP") from a lactic raw material comprising the steps of:

deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5 with the pH being adjusted, if necessary, to the recited range;

contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to remove GMP from the substantially deionized lactic raw material by adsorbing a substantial amount of GMP onto the anionic resin to obtain a treated liquid material that does not contain substantial amounts of GMP;

separating the resin from the treated liquid material;

concentrating the treated liquid material by evaporation and drying; and

recovering GMP by desorbing it from the resin.

9. The process according to claim 8 wherein the step of separating the resin from the treated liquid material is accomplished by filtration or centrifugation and the treated liquid material is dried by spray drying.

10. The process according to claim 1 wherein the anionic resin and the deionized lactic raw material are present in a ratio by volume of between 1:1 and 1:30.

11. The process according to claim 1, wherein the step of separating the adsorbed GMP enriched fraction from the resin is accomplished by:

washing the resin with demineralized water to obtain a wash;

desorbing the GMP from the resin by washing the resin with an acidic, basic or saline aqueous solution rinse to obtain an eluate;

rinsing the resin with demineralized water to obtain a rinse;

combining the eluate, the rinse and the wash;

demineralizing the combined eluate, rinse and wash by ultrafiltration or nanofiltration on a membrane with a mean cut-off region of about 3000 daltons to obtain a retentate and filtrate; and

recovering the GMP enriched fraction as the retentate; and

optionally freeze-drying the recovered retentate.

12. The process according to claim 11 wherein the basic aqueous solution comprises NaOH, KOH or $Ca(OH)_2$, in a concentration of less than 8%.

13. A process for obtaining a fraction of a lactic raw material enriched in glycomacropeptide or caseinoglycomacropeptide ("GMP") comprising the steps of:

deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5 with the pH being adjusted, if necessary, to the recited range;

treating the resin with an alkaline material;

contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to adsorb a substantial amount of GMP onto the anionic resin from the substantially deionized lactic raw material and to obtain a treated liquid material that does not contain substantial amounts of GMP;

separating the resin from the treated liquid material; and

separating the adsorbed GMP enriched fraction from the resin.

14. A process for preparing a composition that contains glycomacropeptide or caseinoglycomacropeptide ("GMP") in combination with a pharmaceutically acceptable carrier, said process comprising the steps of:

(a) deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5 with the pH being adjusted, if necessary, to the recited range;

(b) contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to adsorb a substantial amount of GMP

onto the anionic resin from the substantially deionized lactic raw material and to obtain a treated liquid material that does not contain substantial amounts of GMP;

(c) separating the resin from the treated liquid material;

(d) separating the adsorbed GMP enriched fraction from the resin; and

(e) combining the GMP of step (d) with a pharmaceutically acceptable carrier.

15. The process of claim **14**, wherein the composition is an antithrombotic pharmaceutical composition containing GMP as an antithrombotic agent.

16. A process for obtaining a composition comprising a carrier and a fraction of a lactic raw material enriched in glycomacropeptide or caseinoglycomacropeptide ("GMP"), wherein said process comprises the steps of:

deionizing a lactic raw material for a time sufficient to obtain a substantially deionized lactic raw material having a pH of about 1 to 4.5 with the pH being adjusted, if necessary, to the recited range;

contacting the substantially deionized lactic raw material with an anionic resin having a hydrophobic matrix for a sufficient amount of time and at a sufficient temperature to adsorb a substantial amount of GMP onto the anionic resin from the substantially deionized lactic raw material and to obtain a treated liquid material that does not contain substantial amounts of GMP;

separating the resin from the treated liquid material;

separating the adsorbed GMP enriched fraction from the resin; and

combining said GMP enriched fraction with a carrier;

wherein said process the GMP enriched fraction includes less than 1% by weight of fat, less than 0.2% by weight of lactose, and less than 3% by weight of true whey products.

* * * * *

Please add the following claims:

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